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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,505	05/15/2008	Pascal Paganon	148821-110228	1709

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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03/30/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-at@btlaw.com

Office Action Summary	Application No. 10/595,505	Applicant(s) PAGANON ET AL.	
	Examiner Lindsey Bachman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-24-06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 18 is objected to because of the following informalities: Claim 18 uses a tradename (Parylene) instead of the generic term. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim element “means for ballasting” in Claim 1 is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function.

For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the first pouch" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1-7, 13-17, 19, 20 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Bales et al. (US Patent 6,579,301).

Claim 1, 25: Bales'301 discloses an expandable balloon (12) capable of being implanted inside the stomach (column 2, lines 18-20). The balloon is equipped with a first flexible pocket (inner bladder of balloon 12) that is capable of changing from a folded position to an expanded position (since the balloon 12 is made of a flexible material it is capable of being folded, see column 3, line 37; Figure 1 shows unexpanded configuration and Figure 2 shows the expanded configuration). The balloon enters the expanded configuration by the introduction of an inflation fluid in the first pouch (column 3, lines 35-48). Bales'301 further discloses a ballasting means (14, 22) that has weight and therefore will affect the positioning of the balloon in the stomach.

Claim 2: The ballasting means (14, 22) are integrated with the structure of the balloon (Figures 1 and 2).

Claim 3, 27: Part of the ballasting means (22) are located inside the pouch (inner bladder of balloon 12) of the balloon.

Claim 4: The ballasting means comprise a dense, solid body (14).

Claim 5: The ballasting means comprises a plurality of dense solid bodies (14 and 22).

Claim 6: The solid dense bodies (14 and 22) are connected to one another (Figures 1 and 2).

Claim 7: The solid dense bodies contains a spacer in the form of the volume of element 14 that aids in preventing shocks.

Claim 19: The balloon of Bales'301 is capable of being inflated with a gas (column 4, lines 16-37).

Claim 20: Bales'301 also teaches that the gas that is liquefied in the reservoir by the compressive forces of the pump (column 4, lines 27-37).

ALTERNATE INTERPRETATION

Claim 1: Bales'301 discloses an expandable balloon (12) capable of being implanted inside the stomach (column 2, lines 18-20). The balloon is equipped with a first flexible pocket (inner bladder of balloon 12) that is capable of changing from a folded position to an expanded position (since the balloon 12 is made of a flexible material it is capable of being folded, see column 3, line 37; Figure 1 shows unexpanded configuration and Figure 2 shows the expanded configuration). The balloon enters the expanded configuration by the introduction of an inflation fluid in the first pouch (column 3, lines 35-48). Bales'301 further discloses a ballasting means (22) that has weight and therefore will affect the positioning of the balloon in the stomach.

Claim 13: Bales'301 further discloses a sheath (14) that is capable of containing the ballasting means (22).

Claim 14, 15: The sheath has two ends. One end of the sheath is secured to the balloon at one of its ends (Figure 2). One end of the sheath is outside of the balloon to form a pull tab (Figure 2).

Claim 16: All materials are deformable.

Claim 17: Since sheath (14) is intended for use inside the body, it is formed of a biocompatible material (column 3, lines 41-47).

Claim 1-4, 12-14, 16, 17, 25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai et al. (US Patent 4,739,758).

Claim 1, 25: Lai'758 discloses a balloon (10) capable of being implanted in the stomach. The balloon is equipped with a first pouch (22) capable of changing from a folded position (Figure 6) to an expanded position (Figure 4) via introduction of an inflation fluid into the first pouch (column 4, lines 7-8). The balloon further contains a means for ballasting (24) since it has weight and therefore will affect the positioning of the balloon in the stomach.

Claim 2: The ballasting means are structurally integrated with the balloon (Figure 2).

Claim 3, 27: The ballasting means are located inside the first pouch (Figure 2).

Claim 4: The ballasting means are formed of a solid, dense body (Figure 2).

Claim 12, 28: Lai'758 discloses a second pouch (21) that contains the first pouch (22). The ballasting means (24) are within the second pouch (Figure 2).

Claim 13: Lai'758 discloses a sheath (21) that is capable of containing the ballasting means.

Claim 14: The sheath contains two ends and is secured to the balloon at least one of the two ends (Figure 2).

Claim 16, 17: The sheath is deformable and made of a biocompatible material.

Claims 1-3, 8-11, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster (US Patent 4,485,805) in view of Meyer et al. (US Patent 6,312,405).

Claim 1, 8, 21: Foster'805 teaches a gastric balloon (11) intended to be implanted inside the stomach (Figure 2, 3) and equipped with a first pocket (formed in

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collapsed configuration) capable of changing from a folded position (Figure 2) to an expanded configuration (Figure 3) by introducing an inflation fluid into the pouch through a self-sealing valve (31) (column 6, lines 29-35). The expanded position gives the balloon its functional form. Foster'805 does not teach a means for ballasting.

Meyer'405 teaches a balloon (10) intended for use within the body having a valve (22) that contains an absorbent material that absorbs liquid in the presence of moisture. Since a valve that has absorbed liquid has an increased weight, it is capable of forming a ballast (column 5, lines 20-42). Meyer'405 teaches that it is advantageous to use a hydrophilic material for the valve because this structure and material will result in less resistance on a catheter inserted into the valve when the balloon is being filled. Meyer'405 further teaches that the detachment force needed to detach the balloon from the catheter can be modified (column 5, lines 20-42) with this configuration. It would have been obvious to one of ordinary skill in the art to modify the device taught by Foster'805 with the valve taught by Meyer'405 in order to provide the stated advantages.

Claim 2: The valve (ballasting means) in the device of Foster'805 in view of Myer'405 is structurally integrated with the balloon.

Claim 3: The ballasting means is formed inside the pouch of an unexpanded balloon (Foster'805 Figure 2).

Claim 9, 23: Meyer'405 teaches that the absorbent body is formed by a sponge (column 5, lines 20-28).

Claim 10, 24: Meyer'405 teaches that the sponge is formed of polyvinyl alcohol (column 5, lines 20-28).

Claim 11, 22: Meyer'405 teaches that the body can be formed of sodium polyacrylate polymer (column 5, lines 20-28).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foster'805 in view of Meyer'405, as applied to Claim 1, further in view of Khair et al. (US Patent 5,425,710).

Foster'805 in view of Meyer'405 teach the limitations of Claim 18 except for a Parylene (poly (p-xylylene) polymer coating).

Khair'710 teaches that it is known to provide devices placed into the body with a Parylene coating because Parylene is a known lubricious coating (column 5, lines 21-23). It would have been obvious to one of ordinary skill in the art to modify the device taught by Foster'805 in view of Meyer'405, with a Parylene coating, as taught by Khair'710, in order to provide a lubricious coating on the medical device.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bales'301.

Bales'301 discloses the claimed invention except for the use of tungsten. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use tungsten, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bales'301.

Lai'758 discloses the claimed invention except for the use of tungsten. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use tungsten, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 8:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734
March 26, 2011